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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,817	12/14/2001	James N. Chang	D-3011	5033
33197	7590	03/25/2004	EXAMINER	
STOUT, UXA, BUYAN & MULLINS LLP 4 VENTURE, SUITE 300 IRVINE, CA 92618			FAY, ZOHREH A	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/017,817

Applicant(s)

CHANG ET AL.

Examiner

Zohreh Fay

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Claims 1-34 are presented for examination.

The remarks filed on November 17, 2003 have been received and entered.

Claims 1-5, 7, 9-25 and 31-34 are again rejected under 35 U.S.C. 112 first paragraph for the reasons set forth on page 2 of the office action of August 19, 2003.

Claims 1-34 are rejected under 35 U.S.C. 103 as being unpatentable over Dikstein (U.S. Patent 5,106,615). Diskstein teaches the use of polyanionic polymers such as polyacrylates, cellulose derivatives in an ophthalmic formulation as an artificial tear. See page 3, paragraph 10, page 5, paragraph 21. The above reference also teaches the addition of secondary components such as preservatives and buffering agents. See page 8, lines 39 and 40. The mixture of anionic polymers is also taught by the above reference. See example 3. The above reference differs from the claimed invention in the specific proportions or amounts. It would have been obvious to a person skilled in the art to use the claimed polymers and the mixture thereof in an ophthalmic formulation, considering that the prior art teaches that polyanionic polymers and the mixtures thereof have been previously used in the ophthalmic formulation. The determination of optimum amounts or proportions are considered to be within the skill of artisan in the absence of evidence to the contrary.

One skilled in the art would have been motivated to employ the teachings of the above reference, since it relates to the use of polyanionic agents in ophthalmic formulation. The determination of optimum proportions or amounts are considered to be within the skill of artisan in the absence of evidence to the contrary. Applicant has

presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 1-34 are properly rejected under 35 U.S.C. 103.

Applicant's arguments and remarks regarding the 112 first paragraph rejections have been carefully considered, but are not deemed to be persuasive. Applicant's claims are drawn to the use of the mixture of any polyanionic agent. The specification indicates the use of a few of such compounds. However, such examples are not commensurate in scope with the broad phrases as claimed herein. Since each polymer structure and activity for such agents must be determined from case to case by painstaking experimental study, one of ordinary skill in the art would have been burdened with undue experimentation to determine all the polyanionic polymers and the mixture thereof which would be capable of being used together and be useful as artificial tear for treating dry eye syndrome.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is (703) 308-4604. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z.F

ZOHNNEN FAY
PRIMARY EXAMINER
GROUP 1200

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